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HUSCH & EPPENBERGER, LLC  
190 CARONDELET PLAZA  
SUITE 600  
ST. LOUIS, MO 63105-3441

EXAMINER
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BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/931,466

Applicant(s)

PASKAR, LARRY D.

Examiner

Mark W Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-16 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 23, 25, 27 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-16, 19-22, 24, 26, 28, 29 and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In view of the remarks filed on 10-19-2004, PROSECUTION IS HEREBY REOPENED. A new grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### ***Drawings***

Applicant's proposed drawing correction filed on 5-27-2004 is approved

### ***Claim Rejections - 35 USC § 112***

Claims 22 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 recites a method in which the inner surgical element is fixed into two different out of plane shapes for periods of time that

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permit a medical procedure. The examiner cannot find this sequence of events in the original specification or claims. Claim 22 has similar limitations concerning reforming the inner element into a second shape after a first out of plane fixation step, steps which are not immediately apparent from the original disclosure. The examiner requests applicant to point out the where in the original specification the method comprising this sequence of steps can be found.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganz et al. USPN 4,430,083. Ganz teaches an inner surgical element in the form of either an inner catheters 11a or inner catheter 11b that have a planar bend 103 and transverse distal tips. Tips 105a and 105b are inner catheter curved portions that are transverse to the plane of the bend section 103. (column 7 lines 7-10). Bend sections 101 and 103 are configured to match bend 67a and 109 in such a manner that when inserted the

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sections 101, and 103 find their natural configuration. Therefore outer catheter bend section 67a is also planar with section 103 when the latter is inserted therein. In this regard the examiner considers the outer catheter 57a with the inner catheter(s) 11a or 11b disposed therein to be a combination catheter. Outer catheter tube has distal end portion 67a fixed in a first curve defining a first plane that matches the plane of inner catheter bend 103. The outer catheter is disposed in the body (Column 7 lines 21-22, column 6 lines 6-10) and the inner surgical element having distal end 105 (b) is disposed therein. As the inner catheter is advanced (column 7 lines 23+) the inner catheter bends 101 and 103 become aligned with outer catheter member curves 109 and 67a as tip 105 (105b) emerges from the tip. Such a process involves the formation of the combination catheter in which the shape of the distal end is disposed substantially out of the first plane. Since the catheter and inner surgical element are already being used medically for a catheterization procedure the limitation of "a period of time sufficient to permit medical use of the catheter tube or the inner medical element" is met. However, the inner catheter, being in the correct orientation may be advanced and "positioned" (claim 20) in to the anterior descending artery for performing a thrombus injection treatment procedure. Regarding claim 21 and 22, upon completion of the procedure, the combination catheter would be removed from the patient this would entail the reconfiguration of the combination catheter in a catheterization removal medical procedure.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 14-16, 24-26, 28, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al. USPN 4,430,083 in view of Saice USPN 3,970,089. Applicant differs from Ganz in explicitly stating a fixing step in which the inner surgical element is fixed in an out of plane configuration. Although in all likelihood a fixing step is performed by Ganz for obvious safety reasons as well as need for other equipment such as a angiography injection device to be connected to the catheter requiring inner catheter stability, Ganz et al is silent to such a step. Nevertheless the examiner provides Saice as a secondary reference to show that it was known to provide sealing members within cardiac catheterization sheaths for sealing and immobilizing the inner catheter with respect to the outer sheath (column 3 lines 20-29). Such immobilization thus includes preventing rotation as well as extension of the inner catheter out of the sheath. See column 1 lines 48-54 for the recognized need and benefit for such devices in sheath catheter combinations in 1974, the filing date of Saice. Regarding claim 12, both sheath 57a and inner catheter 11 have preformed curves that are fixed in their distal end portions. Regarding claims 14 and 16, the distal end curve 105 (b) is disposed in the outer sheath during insertion through the sheath and has a step where the inner catheter is extended out the distal end. At that step curves 105 and 67a are adjacent one another and satisfy the conditions set forth in claims 14 and 16. In regard to claims

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31 and 32, the insertion of the inner catheter inside the sheath and tracking along the sheath lumen rotates the inner catheter in a clockwise direction with respect to the outer sheath. (column 7 lines 35-49).

Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al. USPN 4,430,083 in view of Saice USPN 3,970,089 as applied to claim 10 and optionally in further in view of Badger et al USPN 5,030,204. Applicant claims that one of the catheter and the inner element are remotely controllable. The examiner considers the inner element of Ganz to be remotely controllable in the sense stated by applicant on page 5 lines 4-7 of his specification. The curve section (105) of Ganz is remotely controllable by withdrawing and extending the inner element with respect to the outer element, as noted above. Alternatively, as in the embodiments where applicant provides a pull wire, the examiner considers it obvious in view of Badger to include a pull wire in the outer sheath of Ganz to aid in insertion of the catheter and sheath into the ostium by reconfiguring the outer sheath into a tighter curve that provides a force for inserting the inner catheter deeper into the left coronary ostium.

Claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 alone or further in view of Voda USPN 5,401,258. Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083 cited as evidence.

Sylvanowicz uses a catheter/sheath system with a preformed curve providing a fixed outer sheath similar to applicant's teachings on page 9 lines 23-27. Regarding

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claim 19, Sylvanowicz teaches a combination catheter in figure 9 with a fixed curve 60 in outer catheter tube 52 and an inner surgical element in the form of an inner catheter 50 which are disposed in the body together (such as in applicant's specification). The fixed curve 60 can be altered by removing the inner catheter out of the outer catheter to achieve the shape shown in figure 10. The fixed curve portion may also be altered to various shapes by "banking" off different walls for anchoring the catheter in place as applicant himself teaches on page 17 lines 20-23, yet it is still fixed. In this respect Sylvanowicz shows the curve in fixed curve configurations in figures 9-14. The examiner considers the Sylvanowicz catheter's Judkins type curve (60) to provide a fixed curve in a "distal end portion" of the catheter so as to define a plane. (Newly cited Kiemeneij USPN 6723083 at column 1 lines 62 to column 2 line 5 is but one example of one of skill in the art describing a "distal end portion" of a Judkins type catheter as "consisting of a straight portion extending from the shaft portion and followed by a curved portion for approximately 180° followed by a straight portion forming a small angle with the straight portion extending from the shaft portion, this last straight portion terminating in a tip portion substantially perpendicular thereto"). As in applicant's specification, the inner catheter and outer sheath are disposed in the body at the same time thus meeting the disposing steps in the claims. Since the inner catheter is taught to be rotated in going from the left coronary artery to the right, the distal end of the inner catheter will be formed in an out of the plane defined by the outer sheath for a sufficient time to perform medical use of the inner catheter, namely a recatheterization of the coronary arteries by rotation. Alternatively, since the left and the right coronary arteries



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are displaced approximately at 120 degrees apart as seen in Weldon USPN 5,195,990, the inner catheter during these intubation periods of the right or left coronary artery ostia will result in out of plane configurations during at least one of or both of, the intubation orientations. Furthermore, the examiner cites Voda as showing a catheter with a planar body and an out of plane tip to demonstrate that it is possible to have a body that orients the catheter body in one plane within the aortic arch and orients the distal tip out of plane to better align the tip with the coronary artery. Such configurations are seen in figure 4d and 5d of Voda USPN 5,401,258. If not inherent to Sylvanowicz to have an out of plane configuration due to relative orientations of the right and left coronary ostia, it would have been obvious to orient the outer sheath 52 in one plane well and the distal tip of the inner body element in another, particularly when the right and left coronary arteries of the patient are shifted anteriorly or posteriorly as taught by Voda. A medical procedure, namely and contrast media injection is performed during these periods.

Claims 10-16, 22, 24, 26, 28, 29, 31-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 (alone or further in view of Voda USPN 5,401,258) and optionally in view of Saice or Quinn USPN 4,580,573. (Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083 and Carpenter USPN 4,586,491 cited as evidence).

In regard to claim 10, Sylvanowicz teaches a combination catheter in figures 10 and 11 with an outer catheter tube 52 and an inner surgical element in the form of an inner catheter 50. Sylvanowicz considers the entire catheter body to form a modified

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Judkins Left Coronary shaped catheter at its "distal end portion. (See newly cited Kiemeneij USPN 6723083 as explained above). The inner catheter is inserted in the outer catheter member and disposed in the body, namely at the aortic arch of the heart. As shown in figure 12, the catheter is shaped to assume a Judkins left catheter shape. After using the catheter for a medical procedure such as an angiography procedure, the outer catheter is withdrawn proximally so as to reshape the outer catheter fixedly in a manner to orient its distal end portion 62 towards the right coronary artery 9 (figure 13). This shifting is said to also orient the inner catheter distal portion generally towards the right coronary ostium as it is extended towards the ostium, the inner catheter *is then* rotated to insert the tip into the ostia to perform a second medical procedure (figure 14), including performing a second angiography procedure in the right coronary artery.

The fitting 64 which is described to be a similar fitting as in the early embodiment 30 and thus provides an adjustable constricting force to help seal the inner tube. Such constriction also provides friction as one of ordinary skill in the art would recognize. Applicant's state that the term "fixing" should be given its ordinary meaning (page 21 line 1 of the brief) and such meaning would include making firm, stable, or stationary and that no other special meaning should be read into the claim. The examiner believes when Sylvanowicz performs his angiography injections the combination catheter would be stable, firm as well as stationary. The examiner would consider it to be dangerous and against all rationale and wisdom for the device in its final configuration orientation prior to injection or during injection to be unstable, loose, and/or otherwise, moveable. In addition to other stabilizing tasks, the examiner considers it to be inherent or obvious to

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provide enough constricting force upon the gasket member 64 to result in a stable configuration. (Also see newly cited Carpenter USPN 4,586,491 lines 24-31 for explanation as to how gaskets provide stable configurations using friction) Making angiography catheters stable to lessen the recoil effect caused by "jet effect" is a well known step as attested to by applicant himself on page 2 of his specification line 3+.. Optional reference Quinn USPN 4,580,573 is provided as an improvement to the Touchy - Borst type valve used by Sylvanowicz wherein aside from sealing against the inner elements that are inserted into the lumen, they also may be "held in place" column 6 line 38 yet "permitting, if desired, axial movement and rotation of said catheter-like object within said elastic segment". The examiner considers this evidence that the Touchy - Borst valve is considered to be a device for holding catheters and the like in place yet allowing desired manipulation type device thus meeting the ordinary and customary meaning of "fixing". In addition is also considered an obvious substitution to use the valve of Quinn in lieu of the Touchy -Borst for the improved holding and sealing disclosed. The examiner also optionally applies Saice, another introducer type gasket for sealing and holding inner catheters when performing radiopaque injection such as the angiography procedure performed in the Sylvanowicz and Quinn references. In Saice it is taught that the bladder, which operates as a gasket, is inflated to one pressure to allow manipulation of the inner catheter relative to the outer sheath and a second pressure once the catheter is in place and dye is to be injected, to immovably fix the inner catheter with respect to the outer catheter (see column 3 lines 24-29). The examiner considers it obvious for one of ordinary skill in the art to have likewise

tightened down the Touhy- Borst adapter of Sylvanowicz to render the inner catheter immobile during radiopaque dye injection or, alternatively, to have substituted the valve and methods of Saice which offers an alternative configuration for performing dye injections. Substituting one leakage preventing valve for another would be an obvious modification to those of ordinary skill in the art.

Finally, with respect to claim 10, it is considered inherent or otherwise obvious that the inner curve member distal end portion will be fixed in an outer curve. Sylvanowicz method teaches that the outer catheter is merely withdrawn and the inner catheter rotated to access both right and left coronary ostia, the inner catheter curve is either in plane with the outer catheter plane in one configuration and out of plane during the other, or out of plane during both. Either way, it is out of plane during at least one of the procedures. Furthermore, as noted above, the examiner cites Voda as showing a catheter with a planar body and an out of plane tip to demonstrate that it is possible to have a body that orients the catheter body in one plane within the aortic arch and orients the distal tip out of plane to better align the tip with the coronary artery. Such configurations are seen in figure 4d and 5d of Voda USPN 5,401,258. If not inherent, it would have been obvious to orient the body of the outer catheter body portion as well as the distal tip of the inner body portion to access the ostia in an orientation similar to that of Voda with a gripping force that holds the inner catheter configuration.

With respect to claims 11, 24, 26, 28 the examiner notes that that no physician would permit the inner tubes and outer tubes to spin freely relative to one another during injection and would thus provide stability of all components involved. The

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catheter body is typically attached to an angiography injector which holds the catheter in place, i.e. fixes it in place. The gasket member 64 provides friction contributing to the stability. The tubes are remotely controllable to form curves since manipulation at the proximal end by relative sliding and rotation of the tubes with respect to one another results in different curve configurations. Applicant discloses such remote control on page 9, lines 23-27.

With respect to claim 12, both inner and outer catheter members have preformed curves in their bodies.

With respect to claim 13, the inner catheter and outer catheter, the devices are remotely controllable in that withdrawing the inner catheter into the outer catheter beyond the outer catheter curve results a tighter outer catheter as seen in figure 10. In addition when inner catheter curve 57 is withdrawn in to the outer catheter tip, it will either straighten the outer catheter, straighten itself, or do a combination of the two which results in a reconfiguration, much like the embodiments in which applicant perform remote control without the bending wires.

With respect to claims 14 and 16, withdrawing and inserting the inner with respect to outer catheter during insertion or withdraw from the body to aid in transversing the aortic arch would have been obvious, Such a maneuver would bring the inner and outer catheter curves adjacent to one another.

With respect to claim 15, applicant shows an out of plane configuration in their figure 15a with straight portion 35 at about 80-85°. As seen in Weldon, the transition

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going from left to right coronary artery is about 120 degrees assuming first configuration has curves 57 and 60 in same plane. The examiner considers this to be "about 90°". Moreover the the right coronary artery is sometimes shifted as seen in figure 5d of Voda so that it is approximately 90°.

Concerning claims 21 and 22, the step of reforming the distal end of the combination catheter would occur during removal of the distal tip of the catheter member from the right ostia after performing the procedure. Alternatively, and in addressing claim 29, it would have been obvious to treat patients with anterior and posterior displaced right and left coronary arteries as seen in Voda, requiring multiple out of plane configurations during dual angiography.

Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view D'Amelio USPN 4,659,195 and of Ueda 4,617,914. US Patent class/subclass 600/148 and Takahashi reference manual cited as evidence.

Petruzzi et al teach an inner surgical element comprising a catheter with a preformed curve 56 along with a surgical instrument disposed therein, and both further disposed in an outer catheter in the form of a duodenoscope. Since the duodenoscope provides a lumen for the introduction of various instruments and fluids, an endoscope is considered to be a "catheter", however, with additional features. Petruzzi teaches the use of two wheel controls 42 and 42' that permit bending of the distal end of the

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duodenoscope to allow bending to traverse the alimentary tract including the small intestine region. These types of gastroscopes typically provide bending wires that extend from the control wheels to adjacent the distal tip of the catheter body so as to allow the distal tip to be bent as it is steered through the body. Since Petruzzi elects to not show each and every feature of the duodenoscope such as the optic fiber and the control wires, the examiner cites D'Amelio et al USPN 4,659,195 to provide the visual deficiencies of Petruzzi. To have arranged the control wires and the two control wheel elements of Petruzzi in a manner such as those shown in D'Amelio with a multiple plane bending arrangement (figures 5-8 of D'Amelio) would have been conventional. It is noted that the D'Amelio device is also intended for similar medical applications as taught in column 1 lines 5-7, 36-58. The examiner also considers it obvious to include a conventional control wheel braking system as described in Ueda for holding the curve forming wires in bent configurations cites the PTO patent classification system to demonstrate that such devices were so conventional to endoscopes that the USPTO has a subclass specific patents claiming improvements thereto. As can be seen in figure 11 of Petruzzi, the endoscope "outer catheter" is used to position catheter member 56 into the ampulla of Vater, which is an opening located on the rear wall of the duodenum in a highly curved region which tends to curve towards the front of a person near the stomach and back towards the rear as well as to the left side approaching the ileum. This relative location of the ampulla of Vater is shown to some extent by Petruzzi but can better be seen in the three dimensional figure attached to this office action (Takahashi "Atlas of the Human Body"). As a result of the relative positions, it is seen as

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a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right manner relative to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner surgical element , tube 56, snare 58, be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the the ampulla of Vater.

In applying the analysis to the claims, with respect to claim 19, Petruzzi et al shows method in which an outer catheter, in the form of an endoscope 40, positioned in a manner such that it curved with the plane defined by the page, with an inner surgical element tube 56 or element 58 that has been disposed therein and formed in to a shape wherein a distal end of the inner surgical element extends rearwardly into the page to form an out of plane configuration.. While the Petruzzi device is concerned about the stability of the system ( column 4 lines 50- 55) he does not teach that the outer catheter bend is "fixed" within the body. Although, it would seem apparent that such fixing would be required, the examiner notes that Ueda (column 4 lines 65-68) teach that it is well known to provide a brake device to hold curved shapes in an endoscope member. To have provided a braking system to hold the shape of the Petruzzi endoscope in a fixed configuration as shown in figure 11 of Petruzzi and the inner catheter has an out of plane curve configuration, would have been obvious to prevent accidental removal of the inner surgical device or to prevent damage to the tissue. Such holding elements for fixing curves in endoscopes are so notoriously old and well known in the art, they have



their own classification subclass at the USPTO(class 600/148). The method(s) performed in Petruzzi while fixed in the configuration is interpreted as a catheterization procedure and/or an endoscopic procedure (i.e. viewing the ampulla of Vater, or to apply the snare to aid in removing stones. (Claim 20).

In regard to claim 21 , after viewing the ampulla of Vater, and extending the inner surgical element towards the orifice, it would have been obvious to use the bending mechanism (92) to reform the device into a tighter curve to access the opening or to reform it to access that various ducts as taught by Petruzzi..

In regard to claim 22, the Petruzzi inner surgical element , catheter 56 and tool 52 are used in a catheterization procedure as well as a cutting procedure to aid in gall stone removal.

Interpreting the claim language of claims 10 -11, 24, 26, 28, 33, 34 applicant recites "proximally fixing" the distal end portion out of the first plane and fixing it against rotation and translation with respect to the outer catheter. According to Webster's dictionary, "proximally" is defined at or near a point of contact. The examiner considers the side exiting of the inner surgical element, catheter 56 to confine the rotation of the inner element with respect to the outer tube, as argued by applicant, to prohibit and thus fix the inner surgical element in an out of plane configuration against rotation about, and with respect to the outer catheter viewing instrument. When the inner catheter is inserted within the Ampulla of Vater, the catheter would appear to be translationally fixed due to the bending of the catheter against the endoscope body using wedge member 92. Moving the catheter longitudinally would appear to be difficult once the

outer endoscope is set in place. The examiner would also consider it obvious to use a fixing device such as a friction seal in port 48 of the endoscope member to prevent accidental rotation and translation of the catheter tool controller 50 that would result the dislodgement of the inner catheter and tool from the accessed. D'Amellio et al teaches such restricting device for allowing gripping and release of extension elements such as inner catheters and tubes to hold them in position when desired. (column 6 lines 32-40).

Concerning claim 12, the inner catheter 56 is preformed into a curved portion 80 that is thermoset (column 5 lines 15-20)

Concerning claim 13, control wires extend from the control handles (42, 42') to the distal end with the examiner again relying upon D'Amelio for a visual illustration of such conventional endoscope structure.

With regard to claims 14 and 16, viewing figure 11, curve portion 80 and curve portion 30 meet the requirements of the claims curve portion distance from the distal end.

Concerning claim 15, the examiner considers it obvious to position the viewing element and catheter 56 in any out of plane configuration that is necessary to access the Ampulla of Vater. Depending upon the experience of the physician and the shape of the intestines of the specific individual a 90 degree orientation is well within numerous possible configurations for achieving the desired results.

As applied to claim 31, 32, the inner surgical element 56 of Petruzzi is initially withdrawn inside of endoscope catheter 56 and is extended out from the sideport opening. In doing so the inner catheter resumes it's preformed configuration . The distal

tip of the catheter thus rotates with respect to the endoscope body as it is extended and is further rotated by using element 92, see figure 3 with the rotated catheter being shown in the ghost configuration.

Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amelio USPN 4,659,195 in view Ueda 4,617,914 (US class/subclass 600/148) and in further view of Forester et al USPN 4,905,667 or Patel USPN 4,577,621. D'Amelio teaches an endoscope with an inner scope that may be used in the body in the lower gastrointestinal tract, D' Amelio teaches a fixing mechanism 38a and 38b that permits the inner scope to be grasped and released to maintain relative positions of the inner and outer members. Otherwise the inner member may spin freely or be longitudinally extended or retracted. D'Amelio does not teach a mechanism for fixing the outer endoscope in a curved configuration however such mechanisms are conventional and considered obvious to include to maintain stability upon bending as evidenced by Ueda and the cited US patent class/subclass 600/148. Thus the combination of D'Amelio and Ueda possess all of the functions recited in the claims. Forester et al teach the implantation of an inner endoscope member within an outer endoscope member and shows the inner positioned in an out of plane configuration for viewing the gall bladder. To have used the D'Amelio device in the Forester procedure and fixed the inner scope in the extended position as taught by D'Amelio would have been obvious. It would have been obvious to have reconfigured and fixed for inspection, the inner scope for viewing each of the various ducts and

organs desired to be examined. Similarly, the D'Amelio device is useful as a colonoscope and to have fixed the scope in various configurations in the complicated colon passages in various planes to inspect and treat various lesions such as polyps would have been obvious to one of ordinary skill in the art of colonoscopy's given the suggestion of D'Amelio to use his device in such procedures.

### ***Response to Arguments***

Applicant's arguments filed 10-19-2004 have been fully considered but they are not persuasive. Applicant states that the examiner has improperly interpreted the meaning of "distal end portion" with regard to the Sylvanowicz reference. Contrary to applicant's arguments, Kiemeneij (column 1 lines 62 to column 2 line 5) is cited as evidence demonstrating that others skilled in the art would interpret the entire portion of a judkins coronary catheter curve region of Sylvanowicz, including curved and straight portions, as a "distal end portion". The applicant feels that the examiner's interpretation would be strengthened by a showing that such an interpretation is consistent with those of skill in the art. (page 15 of applicant's brief). Kiemeneij provides evidence that the claim language as interpreted by the examiner, would be a consistent interpretation with those of ordinary skill in the art. Moreover, applicant's own figure 15a, which is the only figure to show the claimed out of plane configuration, shows a straight portion 35 on the distal

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end portion of the inner surgical element, which is the same distal end portion the applicant recites in claim 10. In addition, claims 14 and 15 specifically recite that the curves may be spaced up to 3 times the arc length or radius of the smaller of the two curves. Therefore applicant's arguments regarding the examiner's interpretation of the claim language "distal end portion" as being inconsistent with either those recognized in the art or inconsistent with applicant's specification are without merit.

Applicant also takes the position is that Sylvanowicz procedure would require perfect co- planar alignment of the inner catheter versus the outer catheter during both the left coronary artery catheterization as well as the right coronary catheter procedure. The examiner believes that likelihood of such configurations such would be at best ever so slight, and more likely impossible, based upon the prior art of record. No where in the Sylvanowicz disclosure does the Sylvanowicz suggest that both the outer catheter as well as the inner catheter are aligned with tips pointed in the same coplaner direction in a manner suggested by applicant. It is believed that applicant has taken a narrow reading of the reference. The examiner notes that the first passage cited by applicant, results in the configuration as shown in figure 13. "Such withdraw shifts the location of the primary curve proximally along the length of the catheter which cause a repositioning of the distal portion of the inner catheter so that it points toward the right coronary ostium." Thus, the mere repositioning of the catheter from (figure 12) by withdrawing the outer catheter results in figure 13. The inner catheter tip still points away from the right coronary ostium at this point, and Sylvanowicz is generalizing that **the curved portion at area 57 generally points toward the right coronary ostium ,**

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not the tip itself. Applicant's second passage re-emphasizes this point. If one continues to read the next several lines and not stop short where applicant did one finds "thus, when extended, the position of the protruding distal portion of the inner catheter shifts from the position in figure 12 toward a position toward the right coronary ositum." which describes figure 13 with the inner catheter itself extended in a general direction towards the right coronary artery. The tip points away in figure 13 and has to be rotated into the ostium. Continuing with the next line "The inner catheter 50 may be rotated about its longitudinal axis approximately  $180^0$  to direct the distal tip 58 toward the right cornary ostium so that as the distal portion of the catheter 50 continues to shift, it will bring the tip 58 into the right coronary ostium." While Sylvanowicz states " $180^0$ ", the evidence of record suggests that this rotation is more likely about  $120^0$  degrees based upon the disclosure of Weldon USPN 5,195,990 (figure 5) as well as Voda USPN 5445,625 (figures 4a-4d, figures 5a-5d). Thus it is obvious from the collective teachings to rotate the tip in an outer plane configuration, when accessing one of the coronary arteries. The examiner refers back to the rejection above for further discussion.

Applicant's statements on page 18 regarding earlier prosecution histories and their relevance upon the instant application are absurd. The examiner stands by his position that what was shown in the earlier prosecution of the 07/834,007 would not necessarily result in the figure applicant later presented, in particular figure 15a. Such discussion as to why was provided in the examiner's answer in earlier filed application 08/764,745, which applicant chose to abandon.

Applicant's arguments regarding what constitutes "fixing" are not deemed persuasive rebuttals to the art as now applied. The examiner notes applicant's statements on the bottom of page 20 that "There is no indication in the present application that applicant is using "fixing" in any way other than its ordinary of customary meaning - namely, making firm or stable or stationary". In other words applicant's position regarding a proper interpretation of the Sylvanowicz disclosure is that when injecting dye in the coronary arteries using the catheter positioned as in figures 12 and 14, the relationship between the inner catheter and outer catheter in terms of their interaction at the seal member would be soft, unstable and moving. Such a position is irrational. Applicant additionally does understand how the the Touhy Borst adjustable gasket can provide a stable , stationary or firm grasp on the inner catheter though it be designed to allow movement when desired. One of ordinary skill in the art would know how this is accomplished by perusing Quinn patent that has been optionally applied to the claims. The Quinn patent teaches this exact function (column 6, lines 38-46) in a related sealing device. The examiner considers this to be analogous to a vehicle in neutral on a level street, it is firm, stationary and/or stable. However a large enough force applied laterally can move it. The Sylvanowicz adjustable gasket by applying a compressing force operates the same way. It is stable firm and stationary. However enough torquing or pushing force will overcome friction to cause it to move, the amount applied is relative to the degree of compression. This is particularly true of applicant's only disclosed fixing member clamp 103, which is not disclosed as adjustable, but merely provides a frictional gripping force. There is nothing in applicant's disclosure that

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would indicate that applicant's fixing mechanism would operate in any different manner than a frictional gripping manner as does the Touhy-Borst element of Sylvanowicz, except that the Sylvanowicz type structures in general grasp more tightly due to the adjustability of the gripping force. Applicant's clamping device would not prevent movement if a strong enough force were to be applied. Applicant's clamping device can only be designed to exert so much frictional retention force or otherwise it will crush the lumen inside rendering it inoperable. Moreover, the examiner included newly cited Saice USPN 3,979,089 in the rejection of the claims to show that it was common, to adjust the gripping force of these types of seals to from a point that prevents leakage of blood to a point where the inner catheter is immovable to (see column 3 lines 20-29) within an outer catheter member. This is performed particularly when injecting various materials including radiopaque dyes, such as in the angiography procedures that Sylvanowicz discloses.

Regarding applicant's rebuttal regarding the rejections of claims 10-16, 19-22, 24, 26, 28, 29, 31-34 as obvious over Petruzzi USPN 4,474,174, D'Amelio et al USPN 4,695,195 and Ueda USPN 4,617,914 (US patent classification system and Takahashi cited as additional evidence). Applicant argues that there is no indication that the curved tube or tool element 58 will occupy any other plane than that of the catheter scope body 40, yet figures 1 and 11 show that the scope is curved in the plane of the page and that the Ampulla of Vater is positioned on the back wall of the intestine with the inner members 56 and 58 extending backwards towards the opening. Applicant argues that



there is no mechanism to cause the distal end portion to bend in anyway since no control wires are shown figure 3. Many items are not shown in figure 3 including the optics and the control wire for bending the wedge 92. In addition, if the control wires are anchored in the distal tip of the endoscope about a circumference (as the 4 control wires in D'Amelio) wherein the control wire is not within the section shown in the drawings, it will not be seen in the section. It would make sense NOT to put them in the same plane as the wire needed to operate the wedge 92. This would allow 4 directional bending for positioning the endoscope and allow for control of the wedge. This would also allow one to bend the endoscope catheter orthogonally from the direction of the optical system to direct the inner elements 56, and 58 into the ampulla of Vater.

Applicant seems to arguing that only the wedge containing solid member 26 should be considered to be the distal end portion, yet he himself provides disclosure and claim language (claims 14 and 15) that permit spacing from the distal end. Clearly, applicant needs to resolve the many discrepancies in his arguments. Applicant's "looking in one direction and catheterizing in another" are not the examiner's position. The examiner argues that the optics look straight ahead while the device is bent laterally until the ampulla of Vater is observed. Then catheterization takes place.

Applicant argues that the fixing of inner elements relative to an endoscope run contrary to the use of endoscopes. Clearly this is not the case. D'Amelio use a fixing mechanism to hold the the inner scope relative to the outer scope during in retracted and extended positions. The desire to hold inner elements such as other tubes and endoscopes in position is also seen in USPN 4,586,491. This simply is new to the art.

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Moreover, applicant seems to impose a more narrow definition on the term "fixing" as he argues on page 31 lines 10-13 require absolute immobility. This definition is much narrower than applicant's definition of fixing found on page 21 at lines 1-2. The examiner agrees that the original specification should be given the latter meaning since applicant's original specification provides no support for absolute immobilization. Such cannot be achieved with a tube and clamp. Applicant's criticism of the applicant of D'Amelio misses the point of the examiner's application of the art. The examiner applies D'Amelio to provide a visual showing of the components (including the articulating) wire mechanism and the teaching of using a fixing member to hold inner elements in retracted and extended positions. Applicant argues that there is no motivation to combine the teaching of D'Amelio as well as Ueda with the Petruzzi disclosure. The examiner disagrees. Petruzzi recognizes the need to stably position the inner working elements 56 and 58 within the various ducts for treating stones. To have provided such stabilization by fixing the inner tube with respect to the outer tube by using a fixing element to hold the inner member in extended and retracted positions would have been obvious in view of D'Amelio. Likewise to have provided a bending mechanism holding device which were well known as evidenced by Ueda and US patent class/subclass 600/148 to provide the desired stabilization would have been obvious.

The examiner has cited Yoshida USPN 4,593,973 and Strassman USPN 4,838,859 to demonstrate that endoscopes fit into the generally classification of catheters. See Column 1 of Strassman and the well as the use of the term "imaging catheter" by Yoshido.

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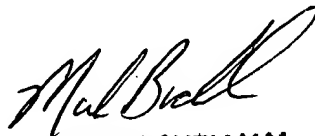
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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MWB

February 5, 2005

  
**MARK BOCKELMAN**  
SENIOR EXAMINER